

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

|  |   |                       |
|--|---|-----------------------|
| MALKA ASHKENAZI, individual, as Personal Representative of the Estate of the Decedent ELI ASHKENAZI, as Guardian for the minor Plaintiff MOTI ASHKENAZI, and HADAS ASHKENAZI (an adult child of the Decedent), all citizens of Israel  | ) | CASE NO.: 08-cv-01767 |
|  | ) | JUDGE JOHN F. GRADY   |
| Plaintiffs,  | ) | JURY TRIAL DEMANDED   |
| v.   | ) |                       |
| BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; BAXTER INTERNATIONAL, INC., a Delaware corporation, successor to IMMUNO-U.S., INC., a Michigan corporation; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation; and ALPHA THERAPEUTIC CORPORATION, a California corporation, | ) |                       |
| Defendants.  | ) |                       |
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**ANSWER, ADDITIONAL DEFENSES, AND JURY DEMAND OF  
DEFENDANT ARMOUR PHARMACEUTICAL COMPANY**

Now comes Armour Pharmaceutical Company (“Armour”), improperly named as “Armour Pharmaceutical Company, Inc.,” and for its answer to plaintiffs’ complaint states as follows:

This Answer is filed on behalf of Armour only, and Armour makes no response to the allegations of plaintiffs’ complaint which are not directed to Armour. Armour responds

herein to the allegations directed to Armour to the best of its ability, but notes that plaintiffs' allegations relate to events that took place between 15 and 27 years ago, and documents related to those events are difficult to locate and may no longer exist, and individuals who may have knowledge of those events may be deceased or may no longer be employed by Armour.

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in Israel and other foreign markets, despite knowledge that the products were manufactured from sick, high risk donors and/or known to be contaminated with the viruses that cause the Human Immunodeficiency Virus and Hepatitis C (now known as "HIV" or "HIV/AIDS" and "HCV" respectively). Defendants continued selling these products to people with hemophilia in Israel and elsewhere even after the products were no longer being used in the United States due to the known risk of HIV/AIDS and HCV transmission. As discussed more fully in paragraphs 66-69, Defendants, such as BAXTER /IMMUNO and CUTTER refused to recall old stocks of products they knew to be contaminated with HIV and HCV both in the United States and abroad even after they had introduced a safer product.

**PARAGRAPH NO. 1 ANSWER:** Armour admits that, at various times, pursuant to license applications approved by the United States Food and Drug Administration ("FDA") and other applicable regulatory bodies, it fractionated, processed, and distributed Factor VIII and Factor IX concentrates and that, pursuant to applicable licenses, Armour's Factor VIII and Factor IX concentrates have been available in countries where they were approved for prescription by licensed physicians for the treatment of hemophilia. Armour denies all remaining allegations of paragraph 1 directed to Armour and states that it acted reasonably at all times with respect to the processing and distribution of its coagulation concentrates. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 which are not directed to Armour, and therefore denies them.

2. Plaintiffs' decedent, ELI ASHKENAZI ("Decedent") had hemophilia, resided in Israel, and contracted HIV and HCV through use of Defendants' contaminated products. Further, Defendants, such as BAXTER/IMMUNO and CUTTER allowed their untreated factor concentrate products to remain on the market in Israel for years

after they were required to begin providing safer, treated factor concentrate products in the United States.

**PARAGRAPH NO. 2 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 concerning plaintiffs' decedent's medical conditions, residency and/or citizenship, and therefore denies them. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 not directed to Armour, and therefore denies them. To the extent paragraph 2 is construed to state factual allegations directed to Armour, they are denied.

3. Defendants manufactured HIV and HCV-contaminated blood factor products at plants in the United States using human plasma taken from thousands of paid American donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the viruses that cause HIV/AIDS and HCV were blood-borne diseases prevalent in such populations. Defendants continued using plasma taken from high risk prison donors, including from prisoners at the notorious Angola prison in Louisiana, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

**PARAGRAPH NO. 3 ANSWER:** Armour denies the allegations of paragraph 3, except that it admits that it processed and distributed anti-hemophilic factor concentrates, and that its concentrates were processed from pooled plasma obtained from qualified donors at FDA-approved plasmapheresis centers and that donors were compensated for the time spent in the plasmapheresis process. Armour specifically denies that it had any duty to provide warnings directly to plaintiffs.

4. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HIV/AIDS and HCV; failed to implement readily available screening tests that would have prevented HIV/AIDS and HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses,

including heat treatment and solvent detergent; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants continued to ship non-heat treated product to Israel and other foreign markets even after ceasing to sell it in the United States, in order to maintain their profit margin on existing contracts and sell off remaining stock no longer marketable domestically. Defendants also continued to sell old stocks of product that had not been treated with solvent detergent both in the United States and abroad, even after introducing a safer product treated with solvent detergent, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HIV and HCV.

**PARAGRAPH NO. 4 ANSWER:** Armour denies the allegations of paragraph 4 and states that it acted reasonably at all times with respect to the processing and distribution of its coagulation concentrates. By way of further answer, Armour states that its factor concentrates were processed and sold in accordance with its FDA-approved licenses and pursuant to and in accordance with all applicable licenses and regulations.

5. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in Israel and elsewhere who were needlessly infected with HIV/AIDS and HCV, including Plaintiffs' Decedent.

**PARAGRAPH NO. 5 ANSWER:** Armour denies the allegations of paragraph 5.

6. Plaintiffs allege an amount in controversy in excess of \$75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

**PARAGRAPH NO. 6 ANSWER:** Armour admits that plaintiffs have alleged that the matter in controversy exceeds the sum of \$75,000, exclusive of interest and costs and that this Court has jurisdiction.

7. Pursuant to this Court's prior Order (attached hereto as Exhibit A), this action should be administratively transferred to MDL 986, pending before the Honorable John F. Grady, since it involves allegations of injuries and damages including HIV, HCV and related complications and injuries as a result of exposure to Defendants' blood factor products.

**PARAGRAPH NO. 7 ANSWER:** Armour admits that transfer of this action to MDL 986, *In re Factor VIII or IX Concentrate Blood Products Litigation*, is proper. Armour states that the remaining allegations of paragraph 7 constitute legal conclusions to which no response is required. To the extent the remaining allegations of paragraph 7 are construed as factual allegations directed to Armour, they are denied.

8. Plaintiffs are informed and believe and upon such information and belief allege that the unlawful, negligent and/or tortious activity alleged herein was carried out predominantly in the United States. Defendants recruited high risk paid donors in the United States and mixed plasma from such donors into the blood pool at their facilities in the United States. Defendants placed misleading labels on their products in the United States and made affirmative misrepresentations regarding their products' safety in the United States, which were relied upon by Plaintiffs and their medical providers. Defendants' decisions to recruit paid donors from high risk populations, to refrain from disclosing the known risks of their products, to forego implementing readily available procedures that would have prevented their products from transmitting HIV/AIDS and HCV, and to ship their products to Israel and other foreign markets even after they could no longer be used domestically were all made in the United States. Defendants' acts of conspiracy, including trade association meetings where they agreed to engage in wrongful conduct, also took place in the United States.

**PARAGRAPH NO. 8 ANSWER:** Armour admits that it collected plasma and processed factor concentrates in the United States. Armour denies all remaining allegations of paragraph 8 and states that it acted reasonably at all times with respect to the processing and distribution of its coagulation factor concentrates.

9. Plaintiffs are informed and believe and upon such information and belief allege that the vast majority of the evidence of the unlawful activity alleged herein is located in the United States. Documents showing Defendants' policies, practices, and decisions regarding recruitment of plasma donors, mixing of plasma into the blood pool at their facilities, labeling of their products, advertising and promotion of their products, disclosure or lack thereof of the risks posed by their products, implementation or lack thereof of procedures to prevent their products from transmitting HIV/AIDS and HCV, and shipment of their products to Israel and other foreign markets are located almost exclusively in the United States. The vast majority of witnesses who will testify to these policies, practices, and decisions are also located in the United States, and would not be subject to subpoena in

other countries. The expert witnesses likely to be presented by both Plaintiffs and Defendants are also located in the United States.

**PARAGRAPH NO. 9 ANSWER:** Armour denies the allegations of paragraph 9, except that it admits that documents concerning the collection of plasma in the United States and processing of factor concentrates in the United States are located in the United States.

10. Most of the relevant medical records regarding the claims of Plaintiffs are located in the United States or have already been brought to the United States and have already been produced to Defendants. Similarly, Plaintiffs have produced or are in the process of preparing for production in the United States Preliminary Patient Profile Forms (“PPPFs”). In addition, witnesses to the Plaintiffs’ damages, such as the Plaintiffs’ family members, are willing to travel to the United States to testify.

**PARAGRAPH NO. 10 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 concerning plaintiffs’ preparation for production of PPFs and the location of plaintiffs’ decedent’s medical records, witnesses, and family members, and therefore denies said allegations. Armour denies that this action is properly brought in the United States, or that all necessary witnesses will be available to testify in the United States.

11. Because the Plaintiffs in this action reside in Israel with a different legal system, litigation in their home country would be costly and inefficient. In addition, Israel is an inadequate alternative forum because of chronic and lengthy court delays, lack of open discovery, unavailability of legal theories, procedures, and remedies, and lack of subpoena power over physical evidence in the United States.

**PARAGRAPH NO. 11 ANSWER:** Armour denies that Israel, which independently regulated the sale of factor concentrates, is an inadequate alternative forum. Armour denies that the fact that plaintiffs reside in Israel and Israel has a different legal system from the United States makes litigation of their claims in Israel costly and inefficient. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding alleged delays, costs,

discovery, legal theories, procedures and remedies, and therefore denies said allegations. With respect to physical evidence in the United States, Armour denies that such evidence would not be available to plaintiffs. Such evidence is already in the possession of plaintiffs' counsel through their participation in MDL-986, and procedures exist to seek discovery of evidence in the United States for cases pending outside the United States.

12. Plaintiffs are informed and believe and upon such information and belief allege that Defendants' unlawful activity was carried out largely in the United States, and, in significant part, in the Northern District of Illinois. Defendant ARMOUR PHARMACEUTICAL COMPANY had its only blood factor manufacturing and processing plant in Kankakee, Illinois, at all pertinent times. This plant was the location of many meetings regarding the processing and research and development of factor concentrates, including meetings in the early 1980s involving discussions about the possible use of solvent detergents in the manufacturing of blood factor concentrates. This plant was also the location of inspections by the United States Food and Drug Administration and Canadian authorities amid reports of viral infections being spread through the use of factor concentrates. In addition, at all times pertinent, ARMOUR PHARMACEUTICAL COMPANY had subsidiary Collection Centers, collecting blood from paid donors, in Illinois.

**PARAGRAPH NO. 12 ANSWER:** Armour admits that it processed and sold factor concentrates pursuant to licenses issued by the FDA and subject to FDA regulation, and that those concentrates were processed in Kankakee, Illinois. Armour denies the remaining allegations of paragraph 12 directed to Armour. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 which are not directed to Armour, and therefore denies them.

13. Defendants BAXTER HEALTHCARE CORPORATION ("BAXTER HEALTHCARE"), BAXTER INTERNATIONAL, INC. ("BAXTER INTERNATIONAL"), and IMMUNO U.S., Inc. ("IMMUNO U.S.") had their headquarters in Illinois at all pertinent times. Defendant BAXTER HEALTHCARE also collected blood from donors in Illinois at all times pertinent, including from donors jailed in the Cook County Jail in the early 1980s.

**PARAGRAPH NO. 13 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13, and therefore denies them.

14. Plaintiffs are informed and believe and upon such information and belief allege that considerable evidence of Defendants' unlawful activity is located, in significant part, in the Northern District of Illinois, where much of the unlawful activity was carried out.

**PARAGRAPH NO. 14 ANSWER:** Armour denies the allegations of paragraph 14 directed to Armour.

15. Plaintiffs are informed and believe and on such information and belief allege that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters locations, or in other facilities within the States of Illinois and California giving these states significant contacts to the claims asserted by Plaintiffs and creating state interests such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair, and Plaintiffs hereby consent thereto.

**PARAGRAPH NO. 15 ANSWER:** Armour denies the allegations of paragraph 15 directed to Armour.

16. The Plaintiffs in this action are as follows:

**PARAGRAPH NO. 16 ANSWER:** Paragraph 16 is not a concise, direct averment of fact to which Armour can reasonably respond. To the extent paragraph 16 is construed to state factual allegations directed to Armour, they are denied.

17. Plaintiff MALKA ASHKENAZI, the surviving spouse of Decedent Eli Ashkenazi, who was a resident of Ness Ziona, Israel and who had hemophilia, and who was infected with HIV and HCV as a result of infusing Defendants' contaminated factor concentrate and/or as a result of Defendants' conspiracy. Plaintiff's Decedent has already provided Defendants with a confidential Preliminary Patient Profile Form (PPF), with beginning Bates number L-PPF 00458; the PPF contains substantial additional information



regarding Plaintiff's claim. Plaintiff MALKA ASHKENAZI resides in and is a citizen of Israel

**PARAGRAPH NO. 17 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 concerning plaintiffs' decedent's medical condition or residency or plaintiff Malka Ashkazi's residency, and therefore denies them. Armour admits plaintiff has provided it with a PPF, but denies plaintiff's PPF provides substantial information regarding his claim. Armour specifically denies all remaining allegations of paragraph 17.

18. Plaintiff MOTI ASHKENAZI is the minor child of the Decedent, and resides in and is a citizen of Israel. Plaintiff MALKA ASHKENAZI is the lawful Guardian of the minor Plaintiff MOTI ASHKENAZI.

**PARAGRAPH NO. 18 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18 concerning plaintiff's residency or relationship between plaintiffs or between plaintiff and the decedent and therefore denies them.

19. Plaintiff HADAS ASHKENAZI is the adult child of the Decedent, and resides in and is a citizen of Israel.

**PARAGRAPH NO. 19 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19 concerning plaintiff Hadas Ashkenazi's residency, citizenship, or relationship to the decedent and therefore denies them.

20. The Plaintiff's Decedent, Eli Ashkenazi, was the beloved husband and father of the Plaintiffs and died on or about March 31, 2007, in Israel, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy. The Decedent resided in and was a citizen of Israel. (Decedent's Death Certificate, the Declarations of Professor Daniel More, Advocate Chen Varshaviak, and Plaintiff Malka Ashkenazi, and the corresponding translator's Certificates of Accuracy, are attached hereto as Exhibit B.

**PARAGRAPH NO. 20 ANSWER:**

Armour admits that plaintiffs attached the aforementioned documents as Exhibit B. However, Armour lacks knowledge or information sufficient to form a belief as to the accuracy of these documents. Armour lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 and any remaining or inconsistent allegations and therefore denies them.

21. Plaintiff's Decedent contracted permanent injuries and diseases, including HIV/AIDS and HCV and associated symptoms and diseases, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy.

**PARAGRAPH NO. 21 ANSWER:** Armour denies the allegations of paragraph 21.

22. Plaintiff's Decedent would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the blood products.

**PARAGRAPH NO. 22 ANSWER:** To the extent paragraph 22 is construed to state factual allegations directed to Armour, they are denied. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. CUTTER, the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. CUTTER was at all pertinent times a citizen of California. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

**PARAGRAPH NO. 23 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23, and therefore denies them.

24. Defendant BAYER, formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant BAYER, at all pertinent times, is and was a citizen of Indiana and Pennsylvania. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as “AHF”) produced from such plasma, to which Plaintiffs’ Decedent was exposed and which contributed directly or indirectly to Plaintiffs’ Decedent's infection with HIV and HCV.

**PARAGRAPH NO. 24 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. Defendant BAXTER HEALTHCARE is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. Defendant BAXTER HEALTHCARE, at all pertinent times, is and was a citizen of Delaware and Illinois. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories and Fenwal Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, which contributed directly or indirectly to Plaintiffs’ Decedent’s infection with HIV and/or HCV.

**PARAGRAPH NO. 25 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25, and therefore denies them.

26. Defendant BAXTER INTERNATIONAL is a Delaware Corporation, and owner and successor in interest to Immuno International A.G. and IMMUNO-U.S. (described hereinafter collectively as “IMMUNO”). BAXTER INTERNATIONAL has its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015, and, on information and belief, is the party liable for the injuries resulting from infusion with Immuno factor concentrates during the relevant period. Defendant BAXTER INTERNATIONAL, at all pertinent times, is and was a citizen of Delaware and Illinois.

**PARAGRAPH NO. 26 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26 and therefore denies them.

27. In 1997, BAXTER INTERNATIONAL acquired all assets and liabilities of Immuno International A.G., an Austrian company that at all times pertinent sold AHF products to Israel and other foreign markets that were produced from human plasma derived from paid donors in the United States. Immuno International A.G. operated in the United States at all times pertinent through its wholly owned American subsidiary Immuno-U.S., located in Rochester, New York. IMMUNO operated 15 processing centers in the United States in the 1980s, which collected plasma from high-risk donors for fractionation in plants located in Rochester, Michigan and Vienna, Austria. These products were then shipped all over the world, and contributed directly or indirectly to Plaintiffs' infection with HIV and HCV. IMMUNO's product names, Bebulin, Feiba, and Prothromplex, are now listed as BAXTER INTERNATIONAL products in the 2003 Registry of Factor Concentrates put out by the World Federation for Hemophilia.

**PARAGRAPH NO. 27 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27 and therefore denies them.

28. IMMUNO-U.S. was a Michigan corporation and was at all pertinent times a United States based operating subsidiary of Immuno International A.G. The most recent corporate filing for IMMUNO-U.S. is the 1998 certificate of merger filed by BAXTER, listing the principal place of business for the surviving entity as One Baxter Parkway, Deerfield, IL, 60015, the same address for Defendants BAXTER INTERNATIONAL and BAXTER HEALTHCARE.

**PARAGRAPH NO. 28 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28 and therefore denies them.

29. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. (described hereinafter as "ARMOUR"), is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania 19426-0107. Defendant ARMOUR, at all pertinent times, is and was a citizen of Delaware and Pennsylvania. Defendant ARMOUR sold AHF products which were produced from human plasma derived from paid donors in the United States. ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and

the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

**PARAGRAPH NO. 29 ANSWER:** Armour admits that it is a Delaware corporation with its principal place of business in New Jersey. Armour further admits that pursuant to product license applications approved by the FDA, it has from time to time processed, distributed and sold Factor VIII and Factor IX concentrates, but denies that such concentrates caused injury as alleged. Armour denies all remaining allegations of paragraph 29.

30. Defendant ALPHA THERAPEUTIC CORPORATION (hereinafter "ALPHA") is a California corporation authorized to do business in all 50 states and the District of Columbia, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. Defendant ALPHA, at all pertinent times, is and was a citizen of California. At all times pertinent Defendant ALPHA has been regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs were exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

**PARAGRAPH NO. 30 ANSWER:** Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30, and therefore denies them.

31. Defendants BAYER, ARMOUR, BAXTER HEALTHCARE, BAXTER INTERNATIONAL, and ALPHA (herein collectively identified as "MANUFACTURERS" or "DEFENDANTS") acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products to Israel and other foreign markets that were contaminated with HIV/AIDS and/or HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution and sale of factor concentrate products to Israel and other foreign markets, or assumed, became or are responsible for the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human

plasma and/or the manufacturing, marketing, distribution or sale of factor concentrate products to Israel and other foreign markets, without limitation thereto..

**PARAGRAPH NO. 31 ANSWER:** Armour admits that, at various times, pursuant to license applications approved by the United States Food and Drug Administration and other governing regulatory bodies, it has fractionated, processed, and distributed Factor VIII and Factor IX concentrates and that such approved concentrates have been available for prescription by licensed physicians. Armour denies that it distributed such concentrates in every country outside the U.S. Armour denies all remaining allegations of paragraph 31.

32. At all times herein mentioned, all Defendants and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and that all Defendants and each of them, thereby ratified those actions..

**PARAGRAPH NO. 32 ANSWER:** Paragraph 32 is not a concise, direct averment of fact to which Armour can reasonably respond. To the extent paragraph 32 is construed to state factual allegations directed to Armour, they are denied.

33. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF," or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Von Willebrand's disease is an inherited hemorrhagic condition similar to hemophilia that affects both men and women. It is characterized by lack of both Factor VIII and another blood protein called von Willebrand's factor.

**PARAGRAPH NO. 33 ANSWER:** Armour admits that hemophilia is a genetic bleeding disorder characterized by a deficiency in one or more of the proteins needed for normal blood clotting. Armour admits that hemophilia type A is characterized by a deficiency of the protein

Factor VIII, and that hemophilia type B is characterized by a deficiency of the protein Factor IX. Armour admits that AHF is a term of art which refers to Factor VIII concentrate. Armour admits that von Willebrand's disease is a genetic disorder characterized by a deficiency of the von Willebrand's protein. Armour lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 33 and therefore denies them.

34. The treatment of hemophilia and von Willebrand's disease involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate, and factor concentrates. Factor concentrates are the product made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

**PARAGRAPH NO. 34 ANSWER:**

Armour admits that the treatment of hemophilia involves the infusion of missing blood proteins and that cryoprecipitate, made from frozen plasma, contains Factor VIII and that fresh frozen plasma contains Factor IX. Armour admits that, at various times, pursuant to license applications approved by the United States Food and Drug Administration and other applicable regulatory bodies, it fractionated, processed, and distributed Factor VIII and Factor IX concentrates. Armour further admits that physicians may prescribe such treatments if indicated for their patients. Armour further admits that individual units of cryoprecipitate or fresh frozen plasma may be from single donors, but states that multiple units from multiple donors are generally required for treatment. Armour denies that its factor concentrates were indicated for the treatment of von Willebrand's disease, and denies all remaining allegations of paragraph 34.



35. By contrast, Defendants in the late 1960s to early 1970s began to market factor concentrates, or AHF, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to twenty thousand donors at a time, a substantial percentage of which were paid donors. These large pools were then subjected to chemical process to concentrate Factors VIII and IX.

**PARAGRAPH NO. 35 ANSWER:**

Armour admits that beginning in 1972 it was licensed by the FDA to process and sell Factor VIII concentrate in the United States, and that beginning in 1984 it was licensed by the FDA to process and sell Factor IX concentrate in the United States. Armour denies that the term “AHF” refers to Factor IX concentrates. Armour admits that factor concentrates represented an advancement in hemophilia treatment over previously available therapies. Armour admits that factor concentrates are derived from pooled human plasma and that plasma donors are compensated for the time involved in the plasmapheresis process. Armour denies all remaining or inconsistent allegations of paragraph 35.

36. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiffs, Plaintiffs’ Decedent or the medical community of these adverse effects, in violation of industry standards and federal regulations.

**PARAGRAPH NO. 36 ANSWER:**

Armour denies the allegations of paragraph 36 except that Armour admits that certain adverse effects of these prescription medications, which risks were present with other blood-based therapies, were known by the medical community and considered in making prescribing decisions. Armour further denies that it owed a duty to provide warnings directly to plaintiffs’ decedent.



37. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference entitled "Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence in patients using Defendants' products of disorders such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

**PARAGRAPH NO. 37 ANSWER:**

Armour admits that the FDA held a conference regarding unsolved therapeutic problems in hemophilia. Armour denies that plaintiffs have accurately characterized the conclusions of the conference, denies that the risks of blood-based therapy were limited to factor concentrates, and denies that the National Blood Policy, which implemented a voluntary donation system for whole blood donors, applied to plasma for further processing. Armour further denies that it recruited donors because of hepatitis exposure. Armour denies all remaining allegations of paragraph 37.

38. Several of the articles from the 1976 conference also raised alarm over the unprecedented convergence of immune disorders in the hemophiliac community, and called for close medical monitoring of the situation...

**PARAGRAPH NO. 38 ANSWER:**

Armour denies that plaintiffs have accurately characterized the articles referenced in paragraph 38. Armour denies all remaining allegations in paragraph 38.

39. At all times material to this Complaint, Defendants failed to adequately warn Plaintiffs, Plaintiffs' Decedent, or his physicians of these serious adverse side effects. Several such adverse effects, including immunosuppression (suppression of the immune system) were not mentioned at all in the Defendants' package inserts, which were required to disclose adverse reactions pursuant to federal statutes and regulations and applicable standards of care. Although Defendants' inserts mentioned a risk that plasma

“may” contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while “hepatitis” simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage, cirrhosis, and significantly elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of the product had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, while failing to disclose that Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded essentially all plasma contaminated by Hepatitis B; and (d) Defendants’ labeling disclosed that the product was made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups available.

**PARAGRAPH NO. 39 ANSWER:** Armour denies the allegations of paragraph 39, and further states that plaintiffs have misleadingly characterized FDA-approved factor concentrate labeling over the 12-year period covered by plaintiffs’ complaint. Armour denies all remaining allegations of paragraph 39 directed to Armour.

40. The demand for and supply of anti-hemophilia [sic] factor rapidly increased during the 1970’s, with the commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of AHF manufactured would increase substantially by 1980. (“Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980,” Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (1977), at page 8; hereinafter “NHLBI Report”).

**PARAGRAPH NO. 40 ANSWER:** Armour admits that at page 8, the NHLBI report stated “[g]iven the prevailing economics of plasma fractionation, the volume of plasma fractionated is governed by demand for albumin, since albumin accounts for an overwhelming proportion of the revenues generated by the sum of end products resulting from plasma fractionation. Over the next five years, demand for albumin is projected to increase at a

moderate rate, and the volume of plasma fractionated is expected to increase accordingly.”

Armour denies all remaining or inconsistent allegations of paragraph 40.

41. In order to sell more AHF to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and even residents of impoverished developing countries such as Haiti and Nicaragua.

**PARAGRAPH NO. 41 ANSWER:**

Armour denies the allegations of paragraph 41.

42. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was available yet for the NANB Hepatitis virus identified in the early 1970's, the only means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

**PARAGRAPH NO. 42 ANSWER:**

Armour denies the allegations of paragraph 42.

43. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of “fractionating” plasma into its various elements. The NHLBI Report noted that, “as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma.” (Id. at 65).

**PARAGRAPH NO. 43 ANSWER:**

Armour admits that plaintiffs have accurately

quoted the NHLBI Report, but denies that plaintiffs have accurately characterized the report. To the extent that paragraph 43 is construed to make factual allegations directed to Armour, they are denied.

44. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is “very expensive.” (Id. at 41). Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. (Id.). The NHLBI Report specifically stated, however, that “plasma collected for high antibody titer cannot be used for fractionation into therapeutic products,” such as Defendants’ factor concentrate. (Id., emphasis added).

**PARAGRAPH NO. 44 ANSWER:**

Armour admits that plaintiffs have accurately quoted the NHLBI Report, but denies that plaintiffs have accurately characterized the report. To the extent that paragraph 44 is construed to make factual allegations directed to Armour, they are denied.

45. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants’ used the same high titer plasma they obtained for making HBIG to manufacture the Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing “as many products as possible from a liter of plasma,” while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

**PARAGRAPH NO. 45 ANSWER:** Armour denies the allegations of paragraph 45.

46. Beginning in about 1978, Defendants BAXTER, CUTTER and ALPHA began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970’s to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

**PARAGRAPH NO. 46 ANSWER:**

Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46, and therefore denies them.

47. It was also well-known in the public health community by the 1970’s that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood, could not be isolated nor identified, and were believed to have serious adverse consequences.

Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

**PARAGRAPH NO. 47 ANSWER:** The allegations of paragraph 47 are not directed to Armour and therefore require no response on behalf of Armour. To the extent that paragraph 47 is construed to state allegations directed to Armour, they are denied.

48. Defendants continued this dual use of high risk plasma even after federal reports warned of the rapid spread of fatal immunosuppressive disease among the same homosexual population from which Defendants heavily recruited. Defendants knew or should have known by no later than the summer of 1981 that urban homosexual males were not “suitable donors” within the meaning of federal regulations and/or other applicable standards of care.

**PARAGRAPH NO. 48 ANSWER:** Armour denies the allegations of paragraph 48.

49. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiffs, Plaintiffs’ Decedent, his physicians, or the FDA.

**PARAGRAPH NO. 49 ANSWER:** Armour denies the allegations of paragraph 49 directed to Armour, and denies that it recruited prisoners as plasma donors. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 49 which are not directed to Armour and therefore denies them.

50. In light of Defendants’ special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) promptly investigate the first reports of opportunistic infections among urban homosexuals in 1981; (b) discontinue the practice of using such high risk donors; (c) disclose the risk to Plaintiffs, Plaintiffs’ Decedent, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (d) implement procedures to kill blood-borne diseases in the products; and (e) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of

high risk donors and resist warnings and recalls, and failed to implement procedures to make their products safe.

**PARAGRAPH NO. 50 ANSWER:** Armour denies the allegations of paragraph 50 and specifically denies that it recruited urban homosexuals and prisoners as plasma donors. Armour specifically denies that it owed any duty to provide warnings directly to plaintiffs' decedent.

51. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral Hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral Hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral Hepatitis by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," NEW ENGLAND JOURNAL OF MEDICINE 1981; 305:1425-1431).

**PARAGRAPH NO. 51 ANSWER:** Armour denies the allegations of paragraph 51.

52. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

**PARAGRAPH NO. 52 ANSWER:** Armour denies the allegations of paragraph 52.

53. Use of the HBc and ALT tests by Defendants by 1981 would have eliminated the vast majority of the transmitters of HIV and HCV from the blood and plasma pools of the nation, before the height of the AIDS and Hepatitis C epidemics. If Defendants had implemented this test in a timely manner, Plaintiffs' Decedent would never have been infected with HIV or HCV as a result of factor concentrate use.

**PARAGRAPH NO. 53 ANSWER:** Armour denies the allegations of paragraph 53.

54. Plaintiffs' Decedent and thousands of other people with hemophilia In Israel and other countries became infected by the AIDS and Hepatitis C viruses through repeated exposures from blood products manufactured from large pools of plasma donors (5,000 to 40,000). If Defendants had used the HBc and ALT tests to decrease

by 70% to 90% the number of HIV and HCV positive donors who went into a pool, the infectivity of the product would have decreased substantially. Consequently, the rate of infection of people with hemophilia would have slowed down enormously, and the medical and scientific community would have been given more time to react appropriately to the HIV and Hepatitis C epidemics.

**PARAGRAPH NO. 54 ANSWER:**

Armour denies the allegations of paragraph 54.

55. As noted below, federal regulations required plasma donors to be in good health, and donors with a “history of viral Hepatitis” were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor which carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

**PARAGRAPH NO. 55 ANSWER:**

Armour admits that its factor concentrates were at all times processed and distributed in accordance with its FDA-approved licenses and pursuant to and in accordance with all applicable regulations. Armour denies all remaining or inconsistent allegations of paragraph 55.

56. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a “surrogate” or “marker” to eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service (“PHS”) on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiffs, Plaintiffs’ Decedent, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for the very diseases that disqualified their plasma. At a January 6, 1983 meeting of Defendants’ trade association, the Pharmaceutical Manufacturer’s Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high risk for AIDS and Hepatitis C transmission.

**PARAGRAPH NO. 56 ANSWER:**

Armour admits that the CDC hosted a meeting of the PHS on January 4, 1983 and the CDC’s summary report of that meeting stated “[a] consensus was reached that it would be desirable to exclude high risk donors to reduce the risk of AIDS



transmission via blood and blood products. However, no consensus was reached as to the best method of doing this.” Armour denies all remaining or inconsistent allegations of paragraph 56.

57. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER’s responsible head Stephen Ojala to various CUTTER executives, reporting back on a meeting held by all Defendants, shows that all Defendants conspired to propose a “task force” to further study the use of HBc as an intentional, bad faith “delaying tactic for the implementation” of the test.

**PARAGRAPH NO. 57 ANSWER:**

Armour admits that in December 1983 the FDA’s Blood Product Advisory Committee created a task force to consider the mechanics and logistics of testing of plasma for pooling and the potential application of anti-HBc (core antibody) as an additional screening test. Armour denies all remaining or inconsistent allegations of paragraph 57.

58. In the late 1970s and early 1980s, it was recognized that viruses were in all AHF products, including Factor VIII and IX. Heat treatment and solvent detergent was available at that time to eliminate many of these viruses, including HIV and HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

**PARAGRAPH NO. 58 ANSWER:**

Armour admits that viral hepatitis was a known and accepted risk of all blood-based therapies in the late 1970s and early 1980s. By way of further answer, Armour states that neither HIV nor HCV had been identified in the late 1970s or early 1980s. Armour denies all remaining or consistent allegations of paragraph 58.

59. The 1977 NHLBI Report noted that albumin, another plasma product, was “heat treated to remove almost all danger of hepatitis.” (Id. at p. 49). Defendant ARMOUR’S memorandum of June 1983 acknowledged that no cases of AIDS had been reported in heat-treated albumin users, but misleadingly states that heat treatment of Factor VIII and IX was not yet feasible. It was clearly known by no later than 1977 that heat treatment was an effective way to make blood products safer, but Defendants wrongfully refused to implement such procedures as to Factor VIII and IX. In 1995, the National



Institutes of Health Institute of Medicine (“IOM”) issued a report on the hemophilia AIDS epidemic which concluded that defendants “did not seriously consider alternative inactivation processes,” including heat treatment, and that “heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980.” Heat treated, HIV-safe factor concentrates were not introduced by any Defendant until 1983, and were not universally in use until 1985.

**PARAGRAPH NO. 59 ANSWER:** Armour admits that albumin, a different blood protein, was heat treated and that as of June 1983, Armour’s application for heat-treated factor concentrate had not been approved. Armour denies that the National Institutes of Health issued the IOM report and that the alternative inactivation processes referenced in the quoted section of IOM report included heat treatment. Armour further denies that Plaintiff has accurately characterized the IOM report. Armour denies the remaining allegations of paragraph 59.

60. In addition to heat treatment, solvent detergent treatment was available to Defendants by the late 1970’s as a simple and effective method of eliminating viruses in their factor concentrate products. Solvent detergent effectively kills viruses such as HIV and HCV by destroying the viruses’ lipid envelope. It is simpler than heat treatment, and unlike heat treatment does not interfere with the Factor VIII and IX proteins needed for blood clotting.

**PARAGRAPH NO. 60 ANSWER:** Armour denies the allegations of paragraph 60.

61. Solvent detergents were well-known, commercially available products as of the 1970’s, and studies in which solvent detergent treatment was used to disrupt viruses were published in the 1970’s in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former BAXTER scientist, received a patent for a solvent detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as “as easy as washing your hands.”

**PARAGRAPH NO. 61 ANSWER:** Paragraph 61 is not a concise, direct averment of fact to which Armour can reasonably respond. To the extent that paragraph 61 is construed to state factual allegations directed to Armour, they are denied.

62. After receiving the patent, Dr. Shanbrom approached various Defendants about implementing the solvent detergent method, but these Defendants wrongfully refused to implement the method. Several of the Defendants refused to even commit any resources to investigate the method. However, in June, 1985, the New York Blood Center (“NYBC”) obtained a license from the FDA to implement the process for Factor VIII. The NYBC obtained a license to use the process in 1987. On information and belief, by 1987, all Defendants except ARMOUR were using the process to virally inactivate their Factor VIII blood products.

**PARAGRAPH NO. 62 ANSWER:**

Armour admits that in 1982 it investigated the potential application of Dr. Shanbrom’s patents. By way of further answer, Armour states that its factor concentrates were processed and sold in accordance with its FDA-approved licenses and pursuant to and in accordance with all applicable licenses and regulations. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations not directed to Armour, and therefore denies them. Armour denies all remaining or inconsistent allegations of paragraph 62.

63. Although heat treatment was effective in destroying the HIV virus, it was ineffective in destroying HCV and HBV. A recent CDC study reported that “84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis . . . several case reports of probable transmission of HBV and HCV through vapor heat-treated and pasteurized products later appeared.” (Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

**PARAGRAPH NO. 63 ANSWER:**

Armour admits that heat treatment was effective in destroying the HIV virus. Armour further admits that paragraph 63 contains a partial quote of a Transfusion article, but denies that plaintiffs have accurately characterized the article. Armour denies all remaining or inconsistent allegations of paragraph 63.

64. The same CDC study reported that “solvent detergent treatment of blood components found to be more effective against enveloped viruses than heat treatment . . . No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients. . .”

**PARAGRAPH NO. 64 ANSWER:**

Armour denies that plaintiffs have accurately quoted or characterized the article referenced in paragraph 64. To the extent that paragraph 64 is construed to state factual allegations directed to Armour, they are denied.

65. The study further reported “in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions.”

**PARAGRAPH NO. 65 ANSWER:** Armour denies that plaintiffs have accurately quoted the article referenced in paragraph 65. To the extent paragraph 65 is construed to state factual allegations directed to Armour, they are denied.

66. The study states further that “the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection.” The study goes on to recommend testing for all people with hemophilia who received infusions of the defendant’s blood products prior to 1992.

**PARAGRAPH NO. 66 ANSWER:** Armour denies that paragraph 66 contains an accurate quote of the Transfusion article or accurately characterizes the article. To the extent paragraph 66 is construed to state factual allegations directed to Armour, they are denied.

67. The failure of Defendants to implement solvent detergent viral inactivation techniques in a timely manner, to warn of the risk that heat treated Factor VIII and IX blood products could transmit HBV and HCV, and to recall heat treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV and HBV after 1983, including Plaintiffs’ Decedent. Even after Defendants knew or should have known that the solvent detergent process effectively destroyed HCV and HBV, as well as HIV, they continued to sell heat treated Factor VIII and IX, and refused to recall these dangerous products from the market.

**PARAGRAPH NO. 67 ANSWER:** Armour denies the allegations of paragraph 67.

68. Between 1983 and 1985, Defendants stopped selling non-heat treated factor concentrate in the United States and introduced a vastly safer heat-treated version. However, one or more Defendants, including BAXTER (successor to IMMUNO) and BAYER (successor to CUTTER) continued to allow their remaining stocks of non-heat treated product to remain on the market in Israel and other countries after ceasing sales of such product in the United States, despite knowledge that the non-heat treated product was contaminated with HIV and/or HCV.

**PARAGRAPH NO. 68 ANSWER:**

Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 68 not directed to Armour, and therefore denies them. Armour admits that it introduced heat-treated factor concentrate in the United States upon its approval by the FDA in January 1984, which concentrate was available only upon the prescription of a physician who determined which product to prescribe. Armour further states that heat-treated concentrates were made available, upon the prescription of a licensed physician, in other countries at such times as they were licensed or otherwise available in accordance with the laws and regulations of those countries. Armour denies all remaining or inconsistent allegations of paragraph 68 directed to Armour.

69. As detailed in this Complaint, by the end of 1982 Defendants' internal communications in the United States revealed their awareness of the AIDS risk posed by their products, but they continued to disavow the connection between AIDS and factor concentrates in their communications to foreign doctors and persons with hemophilia. In mid-1983, months after CUTTER executives authored internal memos expressing their belief that factor concentrates transmitted AIDS, the company wrote a letter to its foreign distributors, in which it characterized the concern over AIDS as an "irrational response," and dismissed the notion that AIDS could be transmitted by factor concentrates as "unsubstantiated speculation." (Internal Defendant documents) CUTTER told the distributors that "[w]hat little evidence exists . . . tends to suggest that AHF concentrates have no direct role in [the AIDS] syndrome."

**PARAGRAPH NO. 69 ANSWER:**

Armour denies the allegations of paragraph 69 directed to Armour. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69 which are not directed to Armour and therefore denies them.

70. Even after Defendants introduced heat-treated products that did not transmit HIV and touted the safety of these new products, they continued selling their contaminated non-HT product abroad.

**PARAGRAPH NO. 70 ANSWER:** Armour admits that its factor concentrates were made available upon the prescription of a licensed physician in such countries and at such times as they were licensed or otherwise available in accordance with the laws and regulations of those countries. Armour denies all remaining or inconsistent allegations of paragraph 70 directed to Armour. Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70 which are not directed to Armour, and therefore denies them.

71. In October of 1984, the CDC issued a report announcing that 74% recipients of Factor VIII concentrates made from plasma derived from American donors were HIV positive. CDC data supports the role American factor played in spreading AIDS among Plaintiffs' Decedent and other persons with hemophilia in Israel. The CDC report also publicized studies showing that heat treatment effectively killed the HIV virus. Upon information and belief, Defendants did not upon receiving this news recall or withdraw their unheated products from Israel. Such products therefore remained on the shelves and continued infecting Israeli hemophiliacs until their expiration dates.

**PARAGRAPH NO. 71 ANSWER:** Inasmuch as it fails to identify the study to which it refers, paragraph 71 is not a concise averment of fact to which Armour can reasonably respond. Armour admits that heat treatment was effective in destroying HIV, and denies all remaining or inconsistent allegations of paragraph 71.

72. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations of the extent of their efforts to assure safety, and fraudulent misrepresentations that understated the risk of AIDS and Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

**PARAGRAPH NO. 72 ANSWER:** Armour denies the allegations of paragraph 72.

73. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report of three people with hemophilia who contracted AIDS. The responsible heads of ARMOUR, ALPHA, CUTTER and BAXTER HEALTHCARE were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. At least three of the Defendants were aware that they had used cryoprecipitate containing plasma from known, targeted homosexuals in the manufacture of Factor VIII and IX blood products. These products had a shelf life of two and three years, respectively, and were either in production or already on the shelves in pharmacies waiting to be infused by people with hemophilia who purchased them. The Defendants involved, BAYER, BAXTER and ALPHA, failed to disclose these facts at the meeting where CDC officials Dr. Don Francis and Dr. Jeff Koplin were present, despite knowledge that the CDC's primary concern at that meeting was the infection of Factor VIII and IX by the transmitter of AIDS, which was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982)

**PARAGRAPH NO. 73 ANSWER:**

Armour denies the allegations of paragraph 73.

74. In or about December, 1982, Rodell, the responsible head for BAXTER HEALTHCARE, entered into an agreement with officials of the FDA to the effect that BAXTER HEALTHCARE would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER HEALTHCARE, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. (BAXTER HEALTHCARE memorandum dated October 20, 1983.)

**PARAGRAPH NO. 74 ANSWER:**

Armour lacks knowledge or information sufficient

to form a belief as to the truth of the allegations of paragraph 74 and therefore denies them.

75. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of four Defendants were present at the meeting with treaters and patients. The purpose of the meeting was to have Defendants' representatives answer patients' questions about AIDS transmission through factor concentrates. A patient asked representatives from CUTTER, ALPHA, ARMOUR and BAXTER the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" No Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Dr. Goodman from BAXTER HEALTHCARE answered regarding BAXTER HEALTHCARE'S use of known homosexuals as follows: "We are changing the nature of questions to homosexuals to the best of our ability." CUTTER'S responsible head, Stephen Ojala, an ALPHA representative, and ARMOUR'S Karl Hansen made no response to the question. This partial and misleading response amounted to concealment of the true risk created by the use of known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

**PARAGRAPH NO. 75 ANSWER:**

Armour admits that an Armour representative attended an informational meeting on January 3, 1983 at Orthopedic Hospital in Los Angeles. Armour lacks knowledge or information sufficient to form a belief that the Orthopedic Hospital meeting was transcribed or that paragraph 75 accurately quotes such transcription, and therefore denies all remaining allegations.

76. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for Factor IX and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5, 1983.)

**PARAGRAPH NO. 76 ANSWER:**

Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 76, and therefore denies them.

77. On January 14, 1983, Dr. Michael Rodell and the other responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). The purpose of the meeting was to have Defendants explain to the NHF what steps they were prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. BAXTER HEALTHCARE, under Rodell's supervision, had already conducted a survey of several of their donor centers to determine how many donors they would lose if the test were implemented. BAXTER HEALTHCARE had decided that up to 16% of their donors would



not pass the test. Further, BAXTER HEALTHCARE's high titered immunoglobulin donors would be eliminated. In order to defer an NHF recommendation that HBc testing be used, Rodell told NHF officials that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc Antibody test as a screening device for donors at high risk for AIDS transmission. The HBc Antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a diagnostic test to be used to ascertain a history of previous hepatitis B infection, and as a screening device for blood and plasma donors. The test had the capability of identifying all donors with a history of viral hepatitis. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

**PARAGRAPH NO. 77 ANSWER:**

Armour admits that Armour representatives attended a January 14, 1983 National Hemophilia Foundation meeting, along with representatives of the Medical and Scientific Advisory Committee of the NHF, the CDC, the NIH, the OoB, the American Red Cross, the CCBC and others and that one purpose of the meeting was to explore the information which was available so that the NHF could issue recommendations to prevent AIDS in persons with hemophilia. Armour denies all remaining or inconsistent allegations of paragraph 77.

78. At the January 14, 1983 meeting, ALPHA, CUTTER and BAXTER concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to the Defendants. CUTTER and ALPHA concealed their extensive use of prison plasma, and BAXTER discussed plans to phase out prison plasma during the coming year. However, none of the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

**PARAGRAPH NO. 78 ANSWER:**

Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 78, and therefore denies them.



79. On or about December 15, 1983, Rodell, then the head of ARMOUR, told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that the Defendants wanted a three month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, the Defendants had agreed to seek the three month hiatus as a “delaying tactic” against implementing the test, and the request for a deferral was made in bad faith (CUTTER memorandum dated December 13, 1983.)

**PARAGRAPH NO. 79 ANSWER:** Armour admits that during a Blood Products Advisory Committee meeting on December 16, 1983, Dr. Michael Rodell suggested that a task force be formed to evaluate, among other things, the feasibility of anticore testing and determine whether such testing would be appropriate. Armour denies all remaining allegations of paragraph 79. Armour specifically denies that the task force was a “delaying tactic” or was formed in “bad faith.”

80. It was strongly suggested by the CDC on July 27, 1982, that AIDS had a viral etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised a substantial portion of CUTTER’S plasma donor sources. CUTTER took no meaningful action to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during the epidemic. In fact, they continued to market products containing plasma from these groups throughout 1982, 1983 and 1984 worldwide. Even more egregiously, CUTTER and other Defendants continued to market high risk non-heat treated factor concentrate abroad after ceasing sales of such product in the United States in favor of vastly safer heat treated product.

**PARAGRAPH NO. 80 ANSWER:** Armour admits that it at all times sold factor concentrates in accordance with applicable licensing, law and regulation, in each country in which such concentrates were sold, and denies all inconsistent or remaining allegations. Armour lacks knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 80, and therefore denies them.

81. Defendants, jointly and individually, fraudulently misrepresented the risk of AIDS and Hepatitis C due to factor concentrates, failed to disclose accurate

warnings of the risk to Plaintiffs, Plaintiffs' Decedent or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high risk donors and by resisting and obstructing HbC testing, heat treatment, and other measures that would truly have reduced the risk.

**PARAGRAPH NO. 81 ANSWER:** Armour denies the allegations of paragraph 81.

82. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*

(a) 21 U.S.C. § 331(b) prohibited [should these be present tense instead?] "adulteration or misbranding of any . . . drug, . . . ."

(b) 21 U.S.C. § 351(a)(2)(B) provided that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety . . . ."

(c) 21 U.S.C. § 352 provided that "[a] drug . . . shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use . . . where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

**PARAGRAPH NO. 82 ANSWER:** Armour admits that paragraph 82 contains some accurate partial quotes of the cited regulations in effect in 1978 through 1990 but denies that

paragraph 82 accurately characterizes the regulations from which it purports to quote. Armour denies any remaining allegations of paragraph 82.

83. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided as follows, with respect to information to be provided with the sale of Defendants' products:

Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

**PARAGRAPH NO. 83 ANSWER:** Armour denies the allegations of paragraph 83.

Armour specifically denies that the cited regulation existed at all times material to plaintiffs' complaint, and specifically denies that the regulation applied to Armour's factor concentrates when it did exist.

84. At all times material to this Complaint, 21 C.F.R. § 200.5 provided as follows:

Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

**PARAGRAPH NO. 84 ANSWER:** Armour admits that paragraph 84 contains an accurate partial quote of the cited regulations in effect in 1978 through 1990. Armour denies any remaining allegations of paragraph 84.

85. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and plasma biologicals.

**PARAGRAPH NO. 85 ANSWER:**

Armour admits that in 1978 through 1990, part 606 of 21 C.F.R. was titled “Current Good Manufacturing Practices for Blood and Blood Components” and Part 640 of 21 C.F.R. was titled “Additional Standards for Human Blood and Blood Products.” Armour denies the remaining allegations of paragraph 85.

86. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided:

Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

**PARAGRAPH NO. 86 ANSWER:**

Armour admits that paragraph 86 contains an accurate quote of 21 C.F.R. §606.140(a), in effect in 1978 to 1990. Armour denies any remaining allegations of paragraph 86.

87. At all times material to this Complaint, 21 C.F.R. § 640.60 defined “Source Plasma (l-human)” as

the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection.

**PARAGRAPH NO. 87 ANSWER:**

Armour denies the allegations of paragraph 87.

88. At all times material to this Complaint, 21 C.F.R. § 640.63(c), entitled “Qualification of Donor,” provided as follows with respect to donors of source plasma:

Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can be determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis;....

Further, 21 C.F.R. § 640.63(a) provided that the method of determining “suitability of a donor” included “tests” as well as the taking of a history and physical examination.

**PARAGRAPH NO. 88 ANSWER:**

Armour admits that paragraph 88 contains an accurate partial quote of 21 C.F.R. §640.63(c), in effect in 1978 through 1990. Armour specifically denies that paragraph 88 accurately characterizes 21 C.F.R. §640.43(a) and denies the remaining allegations of paragraph 88.

89. At all times material to this Complaint, 21 C.F.R. § 606.140 provided as follows:

Laboratory control procedures shall include: (a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent and effective.

**PARAGRAPH NO. 89 ANSWER:**

Armour admits that paragraph 89 contains an accurate quote of 21 C.F.R. §606.140(a), in effect in 1978 to 1990. Armour denies any remaining allegations of paragraph 89.

90. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing “adulterated” products that were unsafe as a result of failure to comply with “Current Good Manufacturing Practice”; (b) marketing “misbranded” products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with the product; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral Hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral Hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure the products were safe.

**PARAGRAPH NO. 90 ANSWER:**

Armour admits that the cited statutes and regulations are, in part, evidence of the standard care. Armour denies the remaining allegations of paragraph 90.

91. Defendants, and each of them, acted in concert and participated in a conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton disregard for the rights and safety of blood product users, in connection with the manufacture of Factor VIII and IX blood products and the collection of constituent plasma.

**PARAGRAPH NO. 91 ANSWER:**

Armour denies the allegations of paragraph 91.

92. Defendants herein, tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate factor concentrates existed in the early 1970s, but was not seriously investigated by any of the Defendants until the early 1980s, despite its effective use in Europe. Use of the HBc antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral Hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS transmission and NANB Hepatitis carriers by 1982, yet no Defendant implemented this test until April 1984.

**PARAGRAPH NO. 92 ANSWER:**

Armour denies the allegations of paragraph 92.

93. Defendants used donors from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV drug abuse was high. After July 1982, when the results of this conduct culminated in reports of fatal immune suppression in three people with hemophilia who infused the product, this concert of action took on a more overt, active form.

**PARAGRAPH NO. 93 ANSWER:**

Armour lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 93 which are not directed to Armour and therefore denies them. To the extent paragraph 93 is construed to state factual allegations directed to Armour, they are denied.

94. By December 1982, the FDA demanded that Defendants stop using prisoners, donors from high risk areas for hepatitis and AIDS transmission, and known

homosexuals. Rather than use good faith efforts to comply with the FDA requests, Defendants collectively argued for a far less onerous and less effective donor screening program. They jointly proposed a system comprised of educating the donor by posting a placard in the donor center stating who the risk groups for AIDS transmission were, and advising the donor that he would be deferred if he acknowledged he was a member of one of those groups. Later, he would be required to fill out a questionnaire in private. If he checked the box indicating he was in a high risk group, he would be permanently deferred.

**PARAGRAPH NO. 94 ANSWER:**

Armour admits that it at all times used plasma that

was collected in accordance with applicable law and regulation and pursuant to FDA licensure.

Armour denies all remaining or inconsistent allegations of paragraph 94 directed to Armour.

95. At a January 6, 1983 meeting of Defendants' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor questionnaires that did little to screen out donors at high risk for AIDS transmission. Defendants further agreed to keep each other informed as to what the other was doing in order that a low standard of care was maintained. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at that time.

**PARAGRAPH NO. 95 ANSWER:**

Armour denies the allegations of paragraph 95.

96. Defendants jointly agreed to oppose recall of the products beginning at the January 6, 1983 meeting at the Pharmaceutical Manufacturers' Association ("PMA"). Beginning with this meeting and continuing through at least July 19, 1983, Defendants met at various times to prepare a strategy to prevent the FDA from advocating a far-reaching recall of factor concentrate products. Defendants knew that due to their high risk donor populations, and their combining of these donors in pools of 5,000 to 40,000, that their products were contaminated with the AIDS agent. Nevertheless, Defendants acted in concert to lobby the FDA, to get the FDA to issue recommendations to limit recalls to circumstances in which an identified donor had died of AIDS within a specified time after the pooling of that donor's plasma. Defendants were well aware that plasma from contaminated asymptomatic donors were mixed in the plasma pools and contaminated virtually all lots. Defendants were successful in deferring any FDA Blood Products Advisory Committee ("BPAC") recommendation for a general recall of the product at the July 19, 1983 BPAC meeting. This joint action allowed the defendants to avoid ever recalling any product except when a donor died of AIDS.



**PARAGRAPH NO. 96 ANSWER:**

Armour denies the allegations of paragraph 96.

97. Defendants conducted a meeting on or about January 6, 1983 at the PMA, a major purpose of which was to decide on a unified strategy to deal with increasing knowledge of risk of AIDS. At the meeting Defendants agreed to postpone submitting any request to the FDA for permission to amend their warning labels or package inserts. They further agreed not to apply to the FDA for warnings enhancements until the other three companies agreed to make application for warning enhancements and to make the warnings similar in content. At the time of the meeting, Defendants had been informed by various reliable health authorities, including the PHS, that there was evidence of an association of risk between factor concentrate use and the transmission of AIDS.

**PARAGRAPH NO. 97 ANSWER:**

Armour denies the allegations of paragraph 97.

98. On December 13, 1983, Stephen Ojala, CUTTER's responsible head, documented by written memorandum that Defendants met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

**PARAGRAPH NO. 98 ANSWER:**

Armour denies the allegations of paragraph 98.

99. Thereafter, at various times throughout 1983-1985, Defendants attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped due to information in the lay press related to AIDS transmission through factor concentrates; to avoid recall of non-heat-treated product after heat-treated products were available; to avoid implementation of the HBc test; and to coordinate a joint legal defense plan in anticipation of litigation from patients afflicted by AIDS through use of the products. Defendants also operated through trade organizations, such as ABRA and PMA, to issue public statements minimizing the risks of AIDS and Hepatitis C and overpromoting the benefits of factor concentrate, to carry out the above-mentioned goals of all Defendants.

**PARAGRAPH NO. 99 ANSWER:**

Armour denies the allegations of paragraph 99.

100. All of the Defendants likely to have caused the harms to Plaintiffs are parties to this lawsuit and properly before the court.

**PARAGRAPH NO. 100 ANSWER:**

Armour denies the allegations of paragraph 100.



101. The conduct of each and all of the Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

**PARAGRAPH NO. 101 ANSWER:** Armour denies the allegations of paragraph 101.

102. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

**PARAGRAPH NO. 102 ANSWER:** Armour denies the allegations of paragraph 102.

103. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

**PARAGRAPH NO. 103 ANSWER:** Armour denies the allegations of paragraph 103.

104. AHF was manufactured using the same fractionation method by all Defendants. As such, during the relevant years from 1975 until 1985, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names of the drugs.

**PARAGRAPH NO. 104 ANSWER:** Armour denies the allegations of paragraph 104.

105. The factor concentrates manufactured by Defendants from 1975 until 1985 contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B, Hepatitis C, and HIV viral transmission. In addition, the factor concentrate was made from large pools consisting of 5,000 to 40,000 paid donors, which further magnified the risk of viral transmission.

**PARAGRAPH NO. 105 ANSWER:** Armour denies the allegations of paragraph 105.

106. None of the factor concentrate was virally inactivated during this time period. Therefore, all of the AHF carried a significant risk of viral transmission. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

**PARAGRAPH NO. 106 ANSWER:** Armour denies the allegations of paragraph 106.

107. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high risk plasma; sale of products abroad known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risks of HIV and HCV transmission from Defendants' contaminated factor concentrate. For example, while the spread of AIDS in homosexuals and IV drug users became known to the FDA and the public, only Defendants knew that these very populations were the donors Defendants were targeting to obtain plasma for their factor concentrate products.

**PARAGRAPH NO. 107 ANSWER:** Armour denies the allegations of paragraph 107.

108. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the risks of HIV and HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiffs' Decedent, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

**PARAGRAPH NO. 108 ANSWER:** Armour denies the allegations of paragraph 108.

109. Until very recently, Plaintiffs had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts – which continue to this day – to give Plaintiffs the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HIV and HCV transmission from their contaminated factor concentrate, Plaintiffs could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiffs have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiffs' claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

**PARAGRAPH NO. 109 ANSWER:** Armour denies the allegations of paragraph 109.

110. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

**PARAGRAPH NO. 110 ANSWER:** In response, Armour incorporates its responses to all previous paragraphs as if fully set forth herein.

111. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiffs and Plaintiffs' Decedent, and knew or had reason to know of the defects in their Factor VIII and/or Factor IX blood products, and that Plaintiffs and Plaintiffs' Decedent would use the blood products.

**PARAGRAPH NO. 111 ANSWER:** Armour admits that it sold factor concentrates in countries in which it was approved and that such concentrates were available for prescription by a licensed physician. Armour lacks knowledge or information sufficient to form a belief as to whether any plaintiffs or plaintiffs' decedent used its factor concentrate. Armour denies all remaining allegations of paragraph 111.

112. Defendants owed Plaintiffs and Plaintiffs' Decedent duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce the blood factor concentrate products in as safe a manner and condition as possible.

**PARAGRAPH NO. 112 ANSWER:** In response to paragraph 112, Armour states that it complied with all applicable duties in connection with the processing and sale of factor concentrate.

113. Specific defects, as specified above in this Complaint, in the blood products, rendered them defective and unreasonably dangerous.

**PARAGRAPH NO. 113 ANSWER:** Armour denies the allegations of paragraph 113.

114. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs' Decedent. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

**PARAGRAPH NO. 114 ANSWER:** Armour denies the allegations of paragraph 114.

115. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Decedent died on or about March 31, 2007.

**PARAGRAPH NO. 115 ANSWER:** Armour denies the allegations of paragraph 115

116. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiffs, individually and as a representatives of Decedent, have been injured and have incurred damages, including but not limited to medical and hospital expenses in the past, past physical and mental pain and suffering, and have suffered loss of financial support, goods and services, consortium, and the loss of familial and emotional love and support.

**PARAGRAPH NO. 116 ANSWER:** Armour denies the allegations of paragraph 116.

117. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

**PARAGRAPH NO. 117 ANSWER:** Armour denies the allegations of paragraph 117.

118. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs' and Plaintiffs' Decedent and was such as warrants an award of punitive damages. WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

**PARAGRAPH NO. 118 ANSWER:** Armour denies the allegations of paragraph 118.

119. For compensatory damages sustained by Plaintiffs, individually and in representative capacity, against all Defendants, jointly and severally, in an amount to be determined at trial;

**PARAGRAPH NO. 119 ANSWER:** Armour denies the allegations of paragraph 119.

120. For punitive and exemplary damages according to proof against all Defendants;

**PARAGRAPH NO. 120 ANSWER:** Armour denies the allegations of paragraph 120.

121. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees;

**PARAGRAPH NO. 121 ANSWER:** Armour denies the allegations of paragraph 121.

122. For injunctive relief in the form of an order requiring Defendants to preserve all relevant documents; and

**PARAGRAPH NO. 122 ANSWER:** Armour denies the allegations of paragraph 122.

123. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

**PARAGRAPH NO. 123 ANSWER:** Armour denies the allegations of paragraph 123.

WHEREFORE, Defendant Armour Pharmaceutical Company prays that plaintiffs' complaint against it be dismissed; that Armour be granted its costs, fees, and expenses incurred herein; and that Armour be granted such other relief as the Court may deem just and proper.

### **ADDITIONAL DEFENSES**

1. The complaint and each and every allegation therein fail to state a claim upon which relief may be granted against Armour.

2. Plaintiffs' claims against Armour are barred by the applicable statute of limitations and/or statute of repose in that they were not commenced within the time prescribed by law.

3. This Court is neither a proper nor convenient forum for the just adjudication of plaintiffs' claims.

4. Joinder of plaintiffs' claims in a single action is prohibited by applicable law, including Federal Rule of Civil Procedure 20.

5. To the extent plaintiffs herein are named plaintiffs in other pending lawsuits against Armour, plaintiffs' claims are not well pled and are barred accordingly.

6. Plaintiffs' claims are barred by the law of Israel, and are as such barred in this Court by principles of comity.

7. The injuries and damages claimed by plaintiffs, if any, were caused in whole or in part by the acts or omissions of persons other than Armour, over whom Armour had no control. Any recovery by plaintiffs should be apportioned in direct proportion to such fault in accordance with applicable law, including 740 ILCS § 100/3.

8. The complaint, and each cause of action purportedly alleged against Armour, are barred, in whole or in part, by plaintiffs' failure to join indispensable parties.

9. Plaintiffs and plaintiffs' agents, including plaintiffs' decedent's physicians, knew and appreciated the risks complained of in the complaint and knowingly and voluntarily assumed such risks, so that any recovery by plaintiffs is barred or should be reduced in accordance with applicable law.

10. Because factor concentrates are prescription biologics available only upon the prescription of a licensed physician, the claims in the complaint against Armour are barred in whole or in part by the learned intermediary doctrine.

11. The claims in the complaint against Armour are barred in whole or in part by federal law pursuant to the Supremacy Clause of the United States Constitution because of the federal regulation and licensing of the collection of plasma and of the processing and distribution of factor concentrates, including but not limited to 42 U.S.C. § 262 and 21 C.F.R. part 600. The claims in the complaint against Armour are preempted by such regulations, as well as by the laws and regulations of Israel, which licensed or otherwise made available factor concentrates to plaintiffs.

12. At all relevant times, any factor concentrate processed and distributed by Armour was processed and distributed in accordance with the applicable state of the art and in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations.

13. The claims in the complaint against Armour are barred in whole or in part by common law or statute and by the applicable blood shield statutes, including 745 ILCS § 40.

14. The alleged damages or injuries were the result of unavoidable circumstances that could not have been prevented by any person, including Armour.

15. Plaintiffs' "market share liability" claims have no applicability under the facts and circumstances of the complaint or under the applicable law, including 745 ILCS 40/2.

16. The injuries and damages claimed by plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any action on the part of Armour was not the proximate and/or competent producing cause of such alleged injuries.



17. The claims in the complaint against Armour are barred by laches, waiver, and/or estoppel.

18. The complaint fails to state a claim against Armour upon which relief may be granted for punitive or exemplary damages.

19. To the extent that the claims in the complaint are based on any theory providing for liability without proof of causation by Armour, no such theory has any application under the facts and circumstances of the complaint under the applicable law, including 745 ILCS § 40/2. In addition, application of any such theory would violate Armour's rights under the United States Constitution or the applicable State Constitution.

20. Any risk associated with any alleged use of Armour's factor concentrates was unavoidable and/or was outweighed by the benefits of factor concentrate.

21. To the extent plaintiffs' allegations refer to or are premised on matters involving von Willebrand's disease, they are irrelevant to plaintiffs' claims and accordingly should be stricken.

22. Armour reserves its right to make a written election of credit for settlements under the applicable law. Armour further demands that its fault and/or responsibility be compared to other parties and non-parties to this suit as provided by any governing statutory or common-law scheme of comparative fault, comparative responsibility and contribution.

23. The complaint fails to state a claim for "willful," "malicious," or "outrageous" conduct against Armour for which relief may be granted.

24. Plaintiffs' claims against Armour under the Illinois Wrongful Death Act, 740 ILCS § 180/2, and the Illinois Survival Act, 755 ILCS § 5/27-6, are barred for lack of standing.

25. To the extent plaintiffs seek to advance claims on behalf of or that are derivative of claims of a decedent, they do not have procedural capacity to do so under applicable law.

26. The alleged injuries or damages of plaintiffs were not caused by Armour, but the acts of plaintiffs' decedent or by factor concentrate which was not processed, distributed, sold, supplied, or in any manner associated with Armour.

27. Armour has not knowingly or intentionally waived any applicable affirmative defenses, and asserts all defenses available under the law of Israel. Armour reserves the right to assert and rely upon such other defenses as may become available or apparent during discovery proceedings or as may be raised or asserted by other defendants in this case.

Dated: August 11, 2008

Respectfully Submitted,

SIDLEY AUSTIN LLP

By: /s/ Tamar B. Kelber

Tamar B. Kelber  
Elizabeth C. Curtin  
Kate J. Grossman  
1 South Dearborn Street  
Chicago, IL 60603  
Telephone: (312) 853-7000  
Facsimile: (312) 853-7036  
Attorneys for Defendants  
Armour Pharmaceutical Company



**JURY DEMAND**

ARMOUR PHARMACEUTICAL COMPANY hereby demands a jury trial on all issues so triable in this action.

Dated: August 11, 2008

Respectfully Submitted,

SIDLEY AUSTIN LLP

By: /s/ Tamar B. Kelber

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Tamar B. Kelber  
Elizabeth C. Curtin  
Kate J. Grossman  
1 South Dearborn Street  
Chicago, IL 60603  
Telephone: (312) 853-7000  
Facsimile: (312) 853-7036  
Attorneys for Defendant  
Armour Pharmaceutical Company

CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of August, 2008, I caused to be served a true and correct copy of the foregoing document by Federal Express overnight, postage prepaid on the following counsel of record:

Elizabeth J. Cabraser  
Morris A. Ratner  
LIEFF, CABRASER, HEIMANN &  
BERNSTEIN LLP  
275 Battery Street, 30<sup>th</sup> Floor  
San Francisco, CA 94111

Sheldon J. Schlesinger  
John Uustal  
SHELDON J. SCHLESINGER, P.A.  
1212 Southeast Third Avenue  
Fort Lauderdale, FL 33316

Richard L. Berkman  
Kathryn Connelly  
DECHERT  
1717 Arch Street  
4000 Bell Atlantic Tower  
Philadelphia, PA 19103

Lindley J. Brenza  
Kaspar J. Stoffelmayr  
BARTLIT, BECK, HERMAN,  
PALENCHAR & SCOTT  
1899 Wynkoop Street, 8<sup>th</sup> Floor  
Denver, Colorado, 80202

Kevin Stack  
KNAPP, PETERSEN & CLARKE  
500 North Brand Boulevard, 20<sup>th</sup> Floor  
Glendale, CA 91203

Geoffrey R.W. Smith  
GEOFFREY SMITH, PLLC  
1350 I Street, N.W., Suite 900  
Washington, DC 20005

/s/ Tamar B. Kelber  
Tamar B. Kelber